

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sudhir V. Shah

Divisional Application of

Application No.: 09/553,496

Filed: April 20, 2000

Title: DIAGNOSIS AND TREATMENT OF HUMAN KIDNEY DISEASES

Date: <u>4/8/04</u>
EXPRESS MAIL LABEL NO. <u>EV05203299805</u>

INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)

☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).

☐ under 37 CFR 1.97(c) together with either:
☐ a Statement under 37 CFR 1.97(e), as checked below, or
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)

☐ under 37 CFR 1.97(d) together with:
☐ a Statement under 37 CFR 1.97(e), as checked below, and
☐ a \$180.00 fee under 37 CFR 1.17(p), or
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)

☐ under 37 CFR 1.97(i):
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
 - ☐ Copies of the cited references are enclosed.
 - ☐ Since this application was filed after June 30, 2003, copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
 - ☒ Copies of the cited references are enclosed in prior application, U.S. Application No. 09/553,496, to which priority under 35 U.S.C. 120 is claimed. The earlier application contains copies of the cited references.
 - ☒ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☒ The "concise explanation" requirement (non-English references) for reference AO under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☒ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []
____ U.S. Patent Application No. [], by [inventor(s)], filed [], Docket No.: []

Examiner

Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

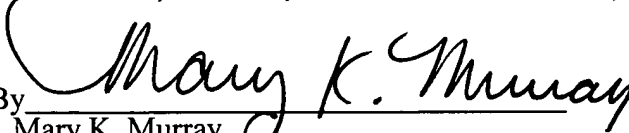
It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By 

Mary K. Murray
Registration No.: 47,813
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Concord, MA 01742-9133

Dated:

April 8, 2004

PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 8, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2629.1003-011
	FIRST NAMED INVENTOR Sudhir V. Shah

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AR	Sumboonnanonda, A., <i>et al.</i> , "Renal tubular function in β -thalassemia", <i>Pediatr Nephrol</i> , 12:280-283.
	AS	Ong-ajyooth, L., <i>et al.</i> , "Renal Function in Adult Beta-Thalassemia/Hb E Disease", <i>Nephron</i> , 78:156-161 (1998).
	AT	Guasch, A., <i>et al.</i> , "Evidence that Microdeletions in the α Globin Gene Protect Against the Development of Sick Cell Glomerulopathy in Humans", <i>J Am Soc Nephrol</i> , 10:1014-1019 (1999).
	AU	Loebstein, R., <i>et al.</i> , "Diabetic Nephropathy in Hypertransfused Patients with β -Thalassemia", <i>Diabetes Care</i> , 21(8):1306-1309 (1998).
	AV	Ongajyooth, L., <i>et al.</i> , "Glomerulonephritis in β -thalassemia Hb-E Disease: Clinical Manifestations, Histopathologic Studies and Outcome", <i>J Med Assoc Thai</i> , 78(3):119-126 (1995).
	AW	Aoki, R.Y., <i>et al.</i> , "Microalbuminuria in Sick Cell Disease", <i>Brazilian J Med Biol Res</i> , 23:1103-1106 (1990).
	AX	Katopodis, K.P., <i>et al.</i> , "Renal Abnormalities in Patients with Sick Cell-Beta Thalassemia", <i>Journal of Nephrology</i> , 10(3):163-167 (1997).
	AY	Pham, P.-T.T., <i>et al.</i> , "Renal abnormalities in sickle cell disease", <i>Kidney International</i> , 57:1-8 (2000).
	AZ	Kontoghiorghes, G.J., <i>et al.</i> , "Simple Synthesis of the Potent Iron Chelators 1-Alkyl-3-hydroxy-2-methylpyrid-4-ones", <i>Inorganica Chimica Acta</i> , 136:L11-L12 (1987).
	AR2	Falk, R.J., <i>et al.</i> , "Prevalence and Pathologic Features of Sick Cell Nephropathy and Response to Inhibition of Angiotensin-Converting Enzyme", <i>The New England Journal of Medicine</i> , 326(14):910-915 (1992).
	AS2	Guasch, A., <i>et al.</i> , "Sickle cell anemia causes a distinct pattern of glomerular dysfunction", <i>Kidney International</i> , 51:826-833 (1997).
	AT2	Cianciulli, P., <i>et al.</i> , "Early detection of nephrotoxic effects in thalassemic patients receiving desferrioxamine therapy", <i>Kidney International</i> , 46:467-470 (1994).
	AU2	Ueda, N., <i>et al.</i> , "Role of 'catalytic' iron in an animal model of minimal change nephrotic syndrome", <i>Kidney International</i> , 49:370-373 (1996).

EXAMINER	DATE CONSIDERED
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PTO-1449 REPRODUCED INFORMATION DISCLOSURE CITATION IN AN APPLICATION April 8, 2004 (Use several sheets if necessary)	ATTORNEY DOCKET NO. 2629.1003-011 FIRST NAMED INVENTOR Sudhir V. Shah
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AV2		Savill, J., <i>et al.</i> , "Mechanisms of glomerular injury". In "Oxford Textbook of Clinical Nephrology," 2 nd ed., pages 404-439, eds., Davidson, A.M., <i>et al.</i> , Oxford Univ. Press (1998).
AW2		Ueda, N., <i>et al.</i> , "In Vivo Evidence for a Role of Reactive Oxygen Metabolites in Glomerular Disease", <i>Kidney: A Current Survey of World Literature</i> , 6:143-146 (1997).
AX2		Boyce, N.W., <i>et al.</i> , "Hydroxyl radical mediation of immune renal injury by desferrioxamine", <i>Kidney International</i> , 30:813-817 (1986).
AY2		Baliga, R., <i>et al.</i> , "Kidney Iron Status in Passive Heymann Nephritis and the Effect of an Iron-Deficient Diet", <i>J Am Soc Nephrol</i> , 7(8):1183-1188 (1996).
AZ2		Shah, S.V., "Evidence suggesting a role for hydroxyl radical in passive Heymann nephritis in rats", <i>The American Physiological Society</i> , F337-F344(1988).
AR3		Thakur, V., <i>et al.</i> , "Evidence suggesting a role for hydroxyl radical in puromycin aminonucleoside-induced proteinuria", <i>Kidney International</i> , 34:494-499 (1988).
AS3		Nankivell, B.J., <i>et al.</i> , "The Role of Tubular Iron Accumulation in the Remnant Kidney", <i>J Am Soc Nephrol</i> , 4(8):1598-1607 (1994).
AT3		Alfrey, A.C., <i>et al.</i> , "Role of iron in the tubulo-interstitial injury in nephrotoxic serum nephritis", <i>Kidney International</i> , 36:753-759 (1989).
AU3		El Nahas, A.M., "Mechanisms of experimental and clinical renal scarring" In: "Oxford Textbook of Clinical Nephrology", 2 nd ed., pages 1749-1788, eds., Davidson, A.M., <i>et al.</i> , Oxford Univ. Press (1998).
AV3		Howard R.L., <i>et al.</i> , "Urinary albumin, transferrin and iron excretion in diabetic patients", <i>International Society of Nephrology</i> , 40:923-926 (1991).
AW3		Olivieri, N.F., <i>et al.</i> , "Iron-Chelation Therapy with Oral Deferiprone in Patients with Thalassemia Major", <i>The New England Journal of Medicine</i> , 918-922 (1995).
AX3		Alfrey A.C., "Toxicity of tubule fluid iron in the nephrotic syndrome", <i>American Journal of Physiology</i> , 263(4):F637-F641 (1992).

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	FIRST NAMED INVENTOR Sudhir V. Shah

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
AY3	Wu, Z-L., <i>et al.</i> , "Iron Loading Enhances Susceptibility to Renal Ischemia in Rats," <i>Renal Failure</i> , 16(4): 471-480 (1994).	
AZ3	Baliga, R., <i>et al.</i> , "In Vitro and In Vivo Evidence Suggesting a Role for Iron in Cistaplin-induced Nephrotoxicity," <i>Kidney International</i> , 53(2): 394-401 (February 1998).	
AR4	Harris, D., <i>et al.</i> , "Mitrochondrial Function in Rat Renal Cortex in REsponse to Proteinuria and Iron," <i>Clinical and Experimental Pharmacology and Physiology</i> 24:916-922 (December 1997).	
AS4	Walker, P.D., <i>et al.</i> , "Evidence Suggesting a Role for Hydroxyl Radical in Gentamicin-Induced Acute Renal Failure in Rats," <i>J Clin Invest</i> 81:334-341 (1988).	
AT4	Shah, S.V., <i>et al.</i> , "Evidence Suggesting a Role for Hydroxyl Radical in Glycerol-Induced Acute Renal Failure," <i>Am J Physiol</i> 255, (<i>Renal Fluid Electrolyte Physiol.</i> 24):F438-F443 (1988).	
AU4	Baliga, R., <i>et al.</i> , "Increase in Bleomycin-Detectable Iron in Ischaemia/Reperfusion Injury to Rat Kidneys," <i>Biochem J</i> 291(3):901-905 (1993).	
AV4	Kontoghiorghese, G.J., <i>et al.</i> , "Studies of Aluminium Mobilization in Renal Dialysis Patients Using the Oral Chelator 1,2-Dimethyl-3-hydroxypyrid-4-one," <i>Arzneim-Forsch/Drug Res.</i> 44(1):522-526 (1994).	
AW4	Baliga, R., <i>et al.</i> , "Oxidant Mechanisms in Toxic Acute Renal Failure," <i>Drug Metabolism Reviews</i> 31(4):971-991 (1999).	
AX4	Walker, P.D., <i>et al.</i> , "Gentamicin Enhanced Production of Hydrogen Peroxide by Renal Cortical Mitochondria," <i>Am J Physiol</i> 253:C495-C499 (1987).	
AY4	Walker, P.D., <i>et al.</i> , "Hydrogen Peroxide Cytotoxicity in LLC-PK ₁ Cells: A Role for Iron," <i>Kidney Int</i> 40:891-898 (1991).	
AZ4	Abul-Ezz, S.R., <i>et al.</i> , "Role of Glutathione in an Animal Model of Myoglobinuric Acute Renal Failure," <i>Proc Natl Acad Sci</i> 88:9833-9837 (1991).	
AR5	Ueda, N., <i>et al.</i> , "Gentamicin-Induced Mobilization of Iron from Renal Cortical Mitochondria," <i>Am J Physiol</i> 265(3 Pt. 2):F435-F439 (1993).	
AS5	Baliga, R., <i>et al.</i> , "Evidence for Cytochrome P-450 as a Source of Catalytic Iron in Myoglobinuric Acute Renal Failure," <i>Kidney Int</i> 49:362-369 (1996).	

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<p>PTO-1449 REPRODUCED</p> <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p>April 8, 2004</p> <p>(Use several sheets if necessary)</p>	<p>ATTORNEY DOCKET NO. 2629.1003-011</p> <p>FIRST NAMED INVENTOR Sudhir V. Shah</p>
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
	AT5	Baliga, R., <i>et al.</i> , "Role of Cytochrome P-450 as a Source of Catalytic Iron in Cisplatin-Induced Nephrotoxicity," <i>Kidney Int</i> 54:1562-1569 (1998).
	AU5	Hanss, B.G., <i>et al.</i> , "The Iron Chelator Deferoxamine Prevents Contrast Media Induced Acute Renal Failure in the Rabbit." Presented at the American Society of Nephrology, 23 rd Annual Meeting, <i>JASN</i> 1(4):612 (1990) (abstract).
	AV5	Baliga, R., <i>et al.</i> , "Role of Iron in Cisplatin-Induced Acute Renal Failure in Rats," <i>J Am Soc Nephrol</i> 7(9):1822 (1996) (abstract).

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Sudhir V. Shah

Divisional Application of

Application No.: 09/553,496

Filed: April 20, 2000

Title: DIAGNOSIS AND TREATMENT OF HUMAN KIDNEY DISEASES

Date: <u>4/8/04</u>
EXPRESS MAIL LABEL NO. <u>EV05203299805</u>

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

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- ☐ under 37 CFR 1.129(a), or
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
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- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
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Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

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 - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
 - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
 - ☐ The "concise explanation" requirement (non-English references) for reference(s) [] under 37 CFR 1.98(a)(3) is satisfied by:
 - ☐ the explanation provided on the attached sheet.
 - ☐ the explanation provided in the Specification.
 - ☐ submission of the enclosed International Search Report.
 - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
 - ☐ the enclosed English language abstract.

[X] Applicant requests that the following non-published pending applications be considered:

Examiner's
Initials

____ U.S. Patent Application No. 09/553,496, by Sudhir V. Shah, filed April 20, 2000, Docket No.: 2629.1003-003

____ U.S. Patent Application No. 10/731,522, by Sudhir V. Shah, filed December 9, 2003, Docket No.: 2629.1003-009

____ U.S. Patent Application No. 10/731,521, by Sudhir V. Shah, filed December 9, 2003, Docket No.: 2629.1003-010

____ By Sudhir V. Shah, filed April 8, 2004, Docket No. 2629.1003-008

Examiner

Date

- [] A copy of each above-cited application, including the current claims, is enclosed.
- [X] A copy of each above-cited application, including the current claims, is enclosed, except U.S. Application No. 09/553,496, to which priority under 35 U.S.C. § 120 is claimed.

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- [] Please charge Deposit Account 08-0380 in the amount of \$[]. A copy of this Statement is enclosed.
- [X] Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Mary K. Murray
Mary K. Murray
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Dated: April 8, 2004

